Figure 1. Generic Attributes of the Risk Assessment Portfolio

Continuum of Assessments

	Screening & Prioritization	Basic Assessment	Intermediate Assessment	Advanced Assessment
Types of available data	Limited hazard or exposure data; generally no human or animal toxicology data, mostly data from alternative sources and predictive models, in vitro toxicokinetic data	Same as Screening and Prioritization; plus limited human or animal toxicology data	Same as Basic; plus more extensive animal toxicology data and may have human, mode of action or in vivo toxicokinetic data	Same as Intermediate; plus extensive human data from epidemiology; likely extensive mode of action or in vivo toxicokinetic data
Resource Requirements	Requires investment in underlying data generation and robust IT infrastructure; assessment activities are primarily computationally derived and will require low staff commitment once established; rapid turnaround	Low to moderate staff commitment depending on extent of data; days to months duration	Moderate staff commitment; several years duration; may or may not have complex modeling	Intensive staff commitment, multi-year duration; involves complex modeling
Types of Issues that Might be Encountered	Extent of data from alternative sources and in vitro toxicokinetic data; availability of appropriate analogs for chemical or biological read-across; domain of applicability for quantitative structure-activity relationship (QSAR); extensive uncertainties; regulatory acceptance; public health emergency situation	Extent of traditional in vivo hazard data; extensive uncertainties; difficulty in characterizing hazard and dose-response with limited evidence; regulatory acceptance due to limited data	Data gaps in traditional in vivo studies; limited mode of action or in vivo toxicokinetic data	Strength of the scientific conclusions; selection of modeling approach(es) and sensitivity analysis; support for cost/benefit analysis; high public health implications
Product[1]	Rank ordering of a large number of chemicals; construction of chemical categories; development of a conservative Point of Departure; relatively high uncertainty; low confidence that may be suitable for purpose	Hazard identification; point of departure based on limited data; may include derivation of reference values and slope factors; high uncertainty; low confidence that may be suitable for the purpose	Hazard identification, point of departure based on multiple data streams; may include derivation of reference values and slope factors; low to medium uncertainty and medium to high confidence	Hazard identification, least uncertain point of departure that may be based on direct human observations and/or extensive modeling; may include derivation of reference values and slope factors; low uncertainty that can likely be characterized; high confidence

[1] Type and level of peer review of various products is commensurate with complexity of the assessment.